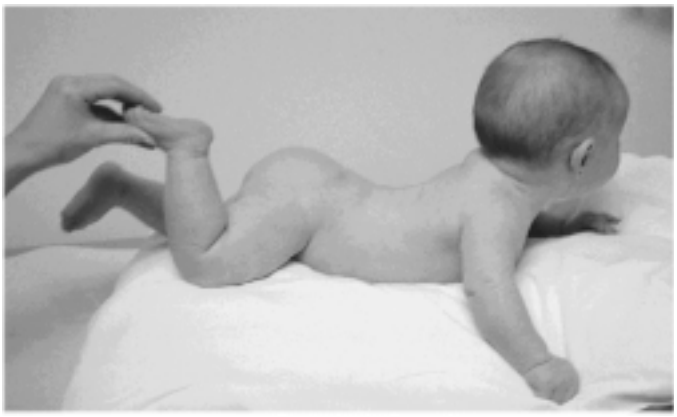


Important Information
for Parents about the

Newborn Screening Test

California
Department of
Health Services

Newborn Screening Program
Genetic Disease Branch
2151 Berkeley Way, Annex 4
Berkeley, CA 94704

NOTICE OF INFORMATION PRACTICES – Effective 01/24/01

THIS NOTICE DESCRIBES HOW YOUR NEWBORN'S MEDICAL INFORMATION MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The California Department of Health Services is authorized to collect information requested by Health and Safety Code Sections 125000, 125025, and 125030. This information is used to identify newborns with inherited or congenital disorders in order to expedite prevention or treatment of the disorder. Provision of this information is required by law (l7CCR 6500 through 6510) and if not provided could result in the death or permanent handicaps for affected newborns.

Uses and Disclosures of Health Information: The California Department of Health Services uses health information about your newborn for screening, to provide health care service, to obtain payment for screening, for administrative purposes, and to evaluate the quality of care that you receive.

We may use the information and specimens obtained by participation in the program for medical research without identification of the person from which they were obtained unless you specifically request in writing they not be used by contacting the person listed below.

The information is otherwise confidential and will not be released without your written permission. If you choose to sign an authorization to disclose information, you can later revoke that authorization to stop any future uses and disclosures by contacting the person listed below. However, we may use or disclose identifiable health information about your newborn without your authorization for several other reasons, as required or permitted by federal and state laws. Subject to certain requirements, we may give out health information without your authorization for public health purposes, for auditing purposes, for approved research studies, and for emergency treatment. We provide information when otherwise required by law, such as for law enforcement in specific circumstances. In any other situation, we will ask for your written authorization before using or disclosing any identifiable health information about your newborn.

We may change our policies at any time. You may request a copy of our current policies at any time. For more information about our privacy practices, contact the person listed below.

Individual Rights: You have the right to look at or receive a copy of your newborn's health information. If you request copies, we will charge you $0.05 (5 cents) for each page. You also have the right to receive a list of instances where we have disclosed health information about your newborn for reasons other than screening, payment or related administrative purposes. If you believe that information in your newborn's record is incorrect or if important information is missing, you have the right to request that we correct the existing information or add the missing information.

You may request in writing that we restrict disclosure of your newborn's information for other than health care, payment and administrative purposes except when specifically authorized by you, when required by law, or in emergency circumstances and request the restriction agreement in writing.

Complaints: If you are concerned that we have violated your newborn's privacy rights, or you disagree with a decision we made about access to your newborn's records, you may contact the person listed below. You also may send a written complaint to the U.S. Department of Health and Human Services. The person listed below can provide you with the appropriate address upon request.

Our Legal Duty: We are required by federal and state law to protect the privacy of your information, provide this notice about our information practices, and follow the information practices that are described in this notice.

For any request for information or action with respect to your medical records maintained by the Genetic Disease Branch of the Department of Health Services, please contact George Cunningham, MD, MPH,Chief, Genetic Disease Branch, 2151 Berkeley Way, Annex 4, Berkeley, CA 94704, 510/540-2552

The California Newborn Screening Test

California state law requires that, before leaving the hospital, your baby must have the Newborn Screening (NBS) Test for:

- PKU (Phenylketonuria)
- Galactosemia
- Primary Congenital Hypothyroidism
- Sickle Cell Disease and other Hemoglobin Diseases

These conditions, if not found and treated very soon after birth, can cause serious health problems. Babies with these conditions may look healthy at birth. Newborn screening can identify babies with these disorders so treatment can start right away.

What is Screening?

Screening tests help identify people of any age who seem healthy but who have a disorder. Newborn screening identifies most, but not all, of the babies born with the disorders screened for by the Newborn Screening Program. Babies also need regular well-baby care to see how the baby is growing, provide immunuzations, and to check for these disorders and other health problems.

Make Sure Your Baby is Tested

Babies can look very healthy at birth and still have a serious disorder. That is why your baby will be tested before leaving the hospital. Effective treatment is available for all of the disorders listed. Early identification and treatment of these disorders can prevent mental retardation and/or life-threatening illness. Babies who receive early and ongoing treatment can grow up to enjoy long, productive lives.

The newborn screening test should be done when babies are between 12 hours and 6 days of age. When the blood is collected before 12 hours of age, the test for PKU is not always accurate. Another blood sample must then be taken to repeat the test. If you leave the hospital or birthing center with your baby before he/she is 12 hours old, you will have to return within the next few days for another test.

Babies not born in the hospital must also have this test. It should be done before your baby is six days old. Call your midwife, the baby's doctor or your local health department to have your baby tested.

The Test Is Safe

A few drops of blood will be taken from your baby's heel. This is a simple and safe test. The blood will be sent to a State-approved lab for testing.

Can I Say No To The Test?

You can only say no for specific religious reasons. If you say "no" you must sign a special form that says your hospital, doctor and the clinic staff are not responsible if your baby develops problems because these disorders were not identified and treated early.

Early Treatment Can Prevent Serious Problems

These disorders can cause serious health problems. Early treatment can prevent many of these problems.

• ***PKU (Phenylketonuria)***
Babies born with PKU have problems when they eat foods high in protein such as milk, including breast milk and formula, meat, eggs and cheese. Without treatment babies with PKU become mentally retarded and/or have other health problems. A special diet can help prevent these problems.

• ***Galactosemia***
Babies with this disorder cannot use some of the sugars in milk, formula and breast milk, and other foods. This disorder harms the baby's eyes, liver and brain. Without treatment, babies with galactosemia can become very sick and die. A special infant formula and diet can help prevent these problems.

• ***Primary Congenital Hypothyroidism***
Babies born with this disorder lack a thyroid hormone. Without this hormone they grow very slowly and become mentally retarded. These problems can be prevented by giving the baby special medicine every day.

• ***Sickle Cell Disease and other Hemoglobin Disorders***
These disorders affect the baby's red blood cells. Babies with sickle cell disease can get very sick and even die from common infections. Many of the infections can be prevented with daily antibiotics. Ongoing health care and close monitoring help children with hemoglobin disorders stay as healthy as possible.

How Can I Get The Results?

If your baby needs more tests you will get a phone call and/or letter with instructions about what to do next. You can get the written test results from your baby's doctor or clinic. It takes about two weeks.

If you move after the test is done, make sure your baby's doctor or the clinic has your new address and phone number.

How Much Does The Test Cost?

The fee is subject to change. Please check with your doctor or hospital for the current cost of the test.

AMERICANS WITH DISABILITIES ACT

Notice and Information Access Statement

Policy of Nondiscrimination on the Basis of Disability and
Equal Employment Opportunity Statement

The Department of Health Services, State of California does not discriminate on the basis of disability in employment or in the admission and access to its programs or activities.

The Deputy Director, Office of Civil Rights, 714 P Street, Room 1050, Sacramento, CA 95814 has been designated to coordinate and carry out the agency's compliance with the nondiscrimination requirements of Title II of the Americans with Disabilities Act (ADA). Information concerning the provisions of the ADA, and the rights provided thereunder, are available from the ADA Coordinator.

Voluntary Supplemental Testing

The Supplemental Testing Program is a research project to evaluate testing methods for identifying several additional metabolic disorders that are currently not a required part of the routine screening program.

Participation in this research study is voluntary. In the hospital, you will be asked to sign a form to let the hospital staff know whether or not you want your baby to participate. Agreeing to participate means that the blood sample already taken for the required screening will be tested for more disorders. There is no additional cost to you or your insurance company, and it does not require taking any more blood from the baby.

What are Metabolic Disorders?

Metabolic disorders affect the body's ability to produce or break down compounds such as proteins, fats or carbohydrates into smaller substances needed by the body for energy, growth and repair. Too much of certain substances and/or too little of others can cause major health problems. If identified early, some of these conditions can be treated before they cause serious health problems. Treatment may include close monitoring of the person's health, medication, dietary supplements and/or special diets.

Metabolic disorders have varying degrees of severity. There could be conditions identified by the study which may not cause significant health problems or require treatment. There may also be disorders identified for which there is no effective treatment.

Will I Find Out My Baby's Results?

Only unusual results will be reported to your newborn's doctor. These are results for which a disorder is suspected and/or additional testing is needed.

VOLUNTARY TESTING

What Happens If a Disorder is Suspected or Results are Unusual?

Your baby's doctor will be contacted if one of the test results is unusual. Further evaluation will be needed to find out if your newborn has a disorder. The baby will be referred to a doctor who specializes in the treatment of metabolic disorders. The specialist will examine the baby and possibly order more tests. If your baby is found to have a disorder, the specialist will assist you and your baby's doctor in treating your baby's special health care needs.

What Are the Benefits of Participating in the Research Study?

If your baby has a metabolic disorder that is not included in the routine newborn screening program, the disorder may be identified by the study. Early identification and treatment of metabolic conditions could prevent physical and mental disabilities and in some cases even death.

By participating in the study, you are helping the California Newborn Screening Program determine which disorders to add to the routine screening in the future. This will benefit newborns with these disorders and their families.

What Are the Risks of Participating in the Research Study?

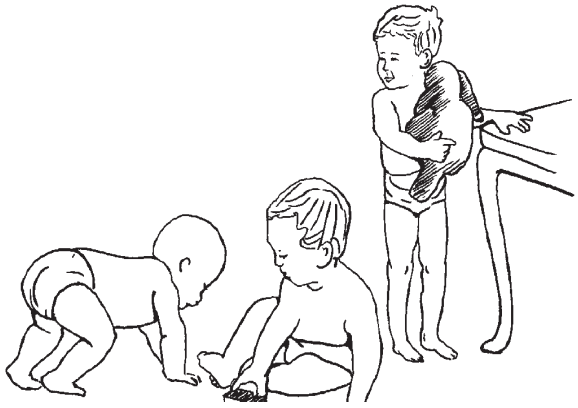
For some babies the optional screening results will indicate that further diagnostic testing is necessary. In most cases, the additional diagnostic testing will show that the baby does not have one of these disorders. Treatment services are not covered by the Newborn Screening Program. These services may be paid for by your health insurance, Medi-Cal or the California Children's Services (CCS) Program. However, the NBS Program will be responsible for costs (including co-payments) associated with the initial diagnostic testing done at a CCS Metabolic Center that are not covered by your health insurance carrier, Medi-Cal, or the California Children's Services

If a blood specimen collected at the hospital is found to be unsuitable for testing, another specimen will be collected and only the required screening test will be done. The optional tests will not be done. In other words, if a baby with an unacceptable specimen has one of the disorders included in the pilot study, the disorder would not be identified by the research study.

The test does not identify all newborns with these conditions. A small number of newborns with one of these disorders will not be identified through this study. Diagnosis and treatment could be delayed until after symptoms appear. Be sure to tell your doctor if your baby does not appear to be well or seems to be developing slower than expected.

What if Someone in Our Family Has a Metabolic Disorder?

Discuss this with your doctor. If there is a family history of a metabolic condition, or a special concern, you should have your baby tested outside of the study. Your doctor can obtain more information on testing laboratories, diagnosis, and treatment of metabolic disorders by contacting one of the California Children's Services Metabolic Centers. A listing of these centers can be obtained by calling (866) 954-BABY (866-954-2229).



CALIFORNIA RESEARCH PARTICIPANT'S

BILL OF RIGHTS

Any person who is asked to participate as a human subject in a research study, or who is asked to consent on behalf of another, has the following rights:

a) Be informed of the nature and purpose of the study.

b) Be given an explanation of the procedures to be followed in the study, and any drug or device to be utilized.

c) Be given a description of any attendant discomforts and risks reasonably to be expected from the study.

d) Be given an explanation of any benefits to the subject reasonably to be expected from the study, if applicable.

e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

f) Be informed of the avenues of medical treatment, if any, available to the subject after the study if complications should arise.

g) Be given an opportunity to ask any questions concerning the study or the procedures involved.

h) Be instructed that consent to participate in the study may be withdrawn at any time and the subject may discontinue participation in the study without prejudice.

i) Be given a copy of the signed and dated written consent form.

j) Be given the opportunity to decide to consent or not to consent to the study without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.